

ISO 9001: 2015 QUALITY MANUAL TEMPLATE FOR SERVICE INDUSTRY

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ABSTRACT

This paper describes a blue print for the Quality Management System (QMS) for a company that is pursuing ISO 9001: 2015 certification. The Quality Manual (QM) proposed in this study could be used as a template to demonstrate an example to follow. The presented example was implemented in a high profile administrative work such as tax administration or medical claim administration. The significant changes in the new ISO 9001 are; risk-based thinking, top management commitment, establishing the context of the organization. Quality procedures are the activities and processes that are the building blocks of the QMS. These activities and processes are intended to fulfil the requirements of the QMS. A medical claim administration, organization will be presented here as an example for a blueprint for QM. This template will ensure that relevant documented quality procedures are available, utilized and adhered to by all its employees in all processes and activities that are relevant to the Quality System.

KEYWORDS : ISO 9001, Quality Management System & Administrative Process

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INTRODUCTION

QSM Template for ISO 9001: 2015

Header Example for the QSM Document

NAME OF COMPANY	Rev X	Effective Date
DOCUMENT TYPE		DD Mmm YY
QUALITY SYSTEM MANUAL DOCUMENT		
	Chg X	Page
CONTROL NUMBER, DOCUMENT TITLE		X of X

Change Control

The first page of the document should indicate the page number and the current change number for that page. The example below demonstrates two sets of Pg# and Change (Chg) lines.

PG#	1	2	3	4	5	6	7	8	9	10	11
CHG	0	1	0	0	1	0	0	0	0	0	0

PG#	12	13	14	15	16	17	18	19	20	21	22
CHG	0	0	2	0	0	0	0	0	0	0	0

Summary of Changes

A summary of all previous changes is kept for historical records. Example of this, summary is shown below.

Issue Date	Issue No.	Change
17 Mar 10	Rev 0	Original
01 Nov 11	Rev 0	1
05 Feb 12	Rev 1	0
08 Apl 12	Rev 1	2

Quality System

The organization has developed and implemented a Quality management System(QMS), based on ISO 9001: 2015 framework that allows the organization to improve its practices through a structured documented system. This will allow the organization to better satisfy the needs and expectations of customers, stakeholders, and interested parties. Our QMS addresses and supports our strategies for designing our services and meeting the high-quality standards that distinguishes us from the competition. Our organization provides administrative services for governmental and non-governmental clients.

Quality Policy

The organization has established a set of processes within the framework of an ISO 9001: 2015 compliant QMS. This is aimed for ensuring quality will be consistently met in all aspects of the administrative services provided. This QMS will also support improvement efforts with a continuous improvement mindset. Our Quality Policy is 100% customer satisfaction; delivery of services will not exceed the agreed upon time period that was specified in the service contract and rules. Furthermore, services will be carried out with the utmost diligence in observing the rules and regulations that are mandated by our clients as well as by our internal quality control system and internal regulations.

Quality Objectives

The Quality Objectives of the organization:

- Close cases in under 30 days 100% of the time.
- Achieve at least 95% confidence in the compliance of the administrative service to the requirements and guidelines.
- Reduce the amount of paperwork that needs reworking to maximum 20%.
- The progress towards achieving these quality objectives will be incorporated in the management review. Quality objectives may vary based on the status and any changes in the company's mission and goals.

Quality Manager

Designated Quality Manager (QM) in charge of the Quality of work in the company with the final approval authority for all Quality Documents is identified.

Quality Manager's Approval Page

This procedure is a Quality System document. It is the holder's responsibility to ensure that any printed copies are the most current version available. The final approval is made by the QM.

- Approved by
- (Signature of QM)

- QM printed name in all caps
- Quality Manager

Quality System Manual

The purpose of this Quality System Manual (QSM) is to outline the QMS of our company. This is a level 1 document and all changes are controlled and approved by the QM. QSM is a document stating the Quality Policy and describing the QMS of the company. The QSM outlines the importance of compliance with customer and regulatory requirements. QMS is complete and responsive to the requirements of the International Organization for Standardization (ISO) 9001:2015.

Company Profile

The organization performs administrative tasks on behalf of its clients. The biggest client that the organization has is the Center for Medicare and Medicaid (CMS), a governmental agency responsible for administering Medicare and Medicaid programs. The organization is responsible for administering Medicare and Medicaid claims on behalf of CMS in 13 states.

SCOPE

The QSM specifies requirements for a QMS that consistently provides products and services that meet customer requirements and enhances customer satisfaction through the effective application of QMS and processes for continuous improvement of the system and the assurance of conformity to customer and any legal and authority requirements. This Quality Manual was created to enable the successful implementation of a QMS, to enable the demonstration of the organization's ability to consistently provide services that meet customer and applicable statutory and regulatory requirements. Managers and team leaders within the organization will find valuable information about our organization's quality policy.

Major Products & Services

The organization provides the following services

- Administrative services such as claims processing, electronic data interchange, provider enrollment and call centers
- Analysis of the population's healthcare needs
- Anti-fraud services

NORMATIVE REFERENCES

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

DEFINITIONS/ACRONYMS

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

ORGANIZATIONAL CONTEXT OF THE ORGANIZATION

The top management of the organization shall determine external and internal issues that are relevant to its purpose and its strategic direction. Internal and external issues are to be viewed considering risk-based thinking. The organization's external issues were identified as; relevant state and government regulations, market competition, risks and opportunities, cultural and social issues, the outlook of the country's economy and technological breakthroughs that enable a higher level of competition, and healthcare laws and regulations. The internal issues that shape the context of the organization is its organizational structure, its culture, its employees' talents, skill sets and expertise, and the performance of its systems. The output of this exercise is used as an input when considering risks and opportunities and the actions needed to address them.

The organizational context is derived from:

- Business plans, strategies, and statutory and regulatory commitments;
- Technology and competitors;
- Economic reports from relevant business sectors;
- Technical reports from experts and consultants;
- SWOT analysis reports;
- Meeting minutes;
- Process maps and reports.

Understanding the Needs and Expectations of Interested Parties

Top management of the organization shall determine the relevant interested parties and their requirements that are necessary for the QMS. The information about these interested parties and their relevant requirements shall be periodically monitored and reviewed.

Internal interested parties:

- Front-Line Staff
- Support Staff
- Middle and upper management.

External interested parties of the organization are:

- Vendors.
- Contractors, such as IT contractors and contractors for other supportive services.
- Customers.
- State and government.

Scope of Quality Management System

The top management of the organization shall determine the boundaries and applicability of the QMS to establish its scope. Factors to consider when considering the scope of the QMS are

- the external and internal issues referred to in clause 1.1
- the determination of the interested parties referred to in 1.2 and their requirements
- The organization's products and services.

The scope of this QMS shall be available and maintained as documented information. The requirements of this QMS shall all be applied unless otherwise stated and justified by the top management of the organization. To justify the irrelevance of any of the requirements stated in this QMS, top management shall show that the requirements in question do not affect the organization's ability or responsibility to ensure the conformity of the its products and services and the enhancement of customer satisfaction.

Quality Management System and its Processes

The organization shall establish, implement, maintain and continually improve a quality

The management system, including the processes needed and their interactions, in accordance with the requirements of the International Standard. To ensure this outcome, the organization shall

- Determine the required process input and the expected process output as well as their sequencing and interactions. This can be accomplished through utilizing methods such as Business Process Mapping and Project Management Process Sequence.
- Determine and apply the criteria and method.
- Determine the resources required.
- Assign responsibilities and authorities.
- Address risk and opportunities, according to the risk-based thinking found in clause 6 of the Quality Standard.
- Evaluate the processes and implement any required changes to ensure the objectives of these processes.
- Continuously improve these processes as well as the QMS itself.

The organization has adopted a process approach to its QMS. The key process groups are

- Leadership and planning processes;
- Customer and stakeholder processes;
- Service development processes;
- Evaluation and improvement processes.

We utilize key performance indicators (KPI) that reflect our objectives to control and monitor our processes. KPI also enables assessments that help in determining the risks and opportunities inherent to each process. We utilize trend

analysis and various indicators with regard to nonconformities. Other relevant data that influence our assessment of our processes are audit results, customer satisfaction data, process performance and the conformity of our services.

LEADERSHIP

Leadership General Requirements

Top management of the organization shall demonstrate its leadership and commitment regarding the QMS by;

- Assuming accountability for the effectiveness of the QMS.
- Verify the existence of a quality policy and quality objectives for the QMS and continue to ensure their alignment and compatibility with the organization's context and strategic direction.
- Assuming accountability for integrating the requirements of the QMS into the organization's business processes.
- Advocating and setting expectations for utilizing process approach and risk-based thinking.
- Provisioning the required resources for the QMS.
- Stressing the prioritization of an effective quality management and the importance of conforming and adhering to the quality management requirements.
- Verify that the QMS is achieving its specified results.
- Continuously engage, direct and support individuals who can contribute to the effectiveness of the QMS.
- Nourishing a culture of improvement.
- Demonstrating leadership through supporting other relevant management roles as it applies to their area of responsibility.

Leadership Customer Focus

The customer is the primary priority of the QMS. Hence, top management will demonstrate leadership and commitment in regard to the customer by:

- Determining, comprehending and consistently meeting all customer requirements as well as applicable statutory and regulatory requirements.
- Determining and addressing risks and opportunities that affect conformity of products and services and the ability to enhance customer satisfaction.
- Maintaining the focus on enhancing customer satisfaction.

Policy

Establishing the Quality Policy

Top management shall set, implement and maintain a quality policy that:

- Suitable for the purpose, context and strategic direction of the organization.
- Can be used as a framework for setting quality objectives.

- Includes a commitment to satisfy applicable requirements.
- Includes a commitment to continual improvement of the QMS.

The Quality Policy statement is

The organization aspires to be the leading and professional services administrator in achieving customer satisfaction by

- Providing excellent standards of quality administrative services which exceeds customer requirements.
- Continuously monitor and fulfil customer required project deadline.

And we are committed to continuously improve the effectiveness of our services by implementing and complying to all requirements required by ISO 9001: 2015 standard.

Communicating the Quality Policy

The quality policy is a document that is:

- Available and maintained as documented information according to clause 4.5 Documented Information of this Quality Manual.
- Communicated, understood and implemented within the organization according to clause 4.3 Awareness of this Quality Manual.
- Available to relevant interested parties, identified in 1.2 of this Quality Manual.

Organizational Roles, Responsibilities and Authorities

Top management shall

- Assign roles, responsibilities and authorities and;
- Ensure that they are communicated and understood within the organization.
- Ensure the conformity of the QMS to the requirements of the ISO 9001 Internal Standard. This will be achieved through a) Internal auditing according to clause 6.2 Internal Audit of this Quality Manual. b) Conducting management reviews according to the clause 6.3 Management Review of this Quality Manual. c) Being aware of every staff according to clause 4.3 Awareness of this Quality Manual.
- Ensure that the processes are delivering their intended outputs. This will be achieved through Business Process Mapping, Project Management Process Sequence.
- Ensure that the processes are delivering their intended outputs.
- Report on the performance of the QMS and on opportunities for improvement, according to clause 7.1 of this Quality Manual.
- Ensure the promotion of customer focus throughout the organization.
- Ensure that the integrity of the QMS is valid and maintained when changes to the QMS are planned and

implemented.

PLANNING

Actions to Address Risks and Opportunities

The organization shall plan for the QMS according to clauses 1.1 and 1.2 of this Quality Manual. The objective of planning shall be to:

- Provide assurance that the QMS will be able to achieve its intended results.
- Enhance the desirable effects.
- Prevent, or reduce, undesirable effects.
- Achieve improvement.

The organization shall plan actions needed to address the relevant risk and opportunities. The organization shall also determine and plan the integration and implementation of these actions into its QMS processes according to clause 1.4 of this Quality Manual. The planned actions shall be proportionate to the anticipated impact on the conformity of products and service

Quality Objectives and Planning to Achieve Them

The organization shall determine and establish quality objectives at the relevant functions, levels and processes needed for the QMS. The organization shall maintain the quality objectives as documented information.

The quality objectives are

- Improve on-time delivery to 100% closing cases within 30 days
- Reduce re-work to 20% of the total volume
- The quality objectives of the organization are:
- Consistent with the quality policy.
- Measurable.
- Considerate of the applicable requirements.
- Relevant to conformity of products and services and to enhancement of customer satisfaction.
- Monitored.
- Communicated.
- Updated as appropriate.

The plan on achieving the quality objectives of the organization shall determine;

- Required actions.
- Required resources.

- Responsible persons.
- Completion timeline.
- Evaluation of results.

Planning Of Changes

The organization shall carry out changes to the QMS when necessary in a planned manner according to clause 1.4 of this Quality Manual.

When planning for changes, the organization shall consider:

- The purpose of the changes and their potential consequences.
- QMS integrity
- Resources availability.
- The allocation or reallocation of responsibilities and authorities.

SUPPORT

Resources

General

The resources needed for establishing, maintaining and continually improving the quality manual system shall be determined by the organization. The organization shall consider the capabilities and constraints related to the existing internal resources and what is needed from external providers.

People

The organization shall determine and provide the required personnel for the effective implementation of its QMS and for the operation and control of its processes.

The required qualifications of the personnel will be addressed in clause 4.2 of this Quality Manual. The numbers of required personnel shall be determined based on both anticipated demand and processing time.

Infrastructure

The organization shall ensure that the infrastructure that is determined to be necessary for the operation of its processes and for the achievement of conformity of products and services is provided and maintained.

The infrastructure includes

- Buildings and associated utilities;
- All equipment, including hardware and software;
- Transportation resources available from within the company or through a third party that the company contracts with.
- Information and communication technology.

Environment for the Operation of Processes

The necessary environment for the operation of the organization's processes shall be determined and provided by upper management with the purpose of achieving conformity of products and services. The necessary social environment is non-discriminatory, calm, non-confrontational, and team orientated. The necessary psychological environment is a stress-reducing, non-threatening or intimidating. The necessary physical environment in the organization in all its buildings is temperature, heat, humidity, light, airflow.

Monitoring and Measuring Resources

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to the requirements.

These resources that are provided for monitoring and measurement will be:

- Suitable for the specific type of monitoring and measurement activities being undertaken;
- Maintained to ensure their continuing fitness for their purpose.

Appropriate evidence of fitness of the monitoring and measurement shall be retained as documented information according to Documented Information Control Procedure.

Measurement Traceability

Measurement traceability is required internally within the organization for the purpose of tracking labour efficiency, tracking service quality and determining performance trends. The measurement of labor efficiency occurs through employee submitted information regarding the process or service time. Measurement of quality of service occurs through sampling by a quality auditor of results of finished processes. There are clear and written checklists that the quality auditor goes through to verify the quality of work. Whether the measurement is self-reported, automated or performed through an auditor, all measurement equipment and processes shall be calibrated or verified or both, at specified intervals, or prior to use, against measurement standards traceable to:

- Customer requirements;
- Internal quality requirements;
- Relevant International Standards.

The relevant requirements or standards that are being traced to shall be retained as documented information. Measuring equipment and processes shall be identified and their status shall be clearly determined. Safeguards shall be in place to prevent any adjustments, malfunctioning, damage or deterioration in measurement equipment of processes so as to protect the validity and verifiability of the measurement results.

Organizational Knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge will be available to the relevant parties and maintained in a specified repository. In order to address the changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

Competence

Competence shall be determined based on the respective Job Description (JD). The JD shall elaborate the qualifications needed for staff performing work under their control that affects the performance and effectiveness of the QMS. Competence shall be determined and revised in the event that an issue has been raised from Control of Non-Conformity Procedure.

The organization shall

- Determine the necessary competence for each position for achieving the required level of performance and effectiveness of the QMS.
- Ensure that the individuals currently performing work, will be assigned work in the future or engaging the QMS in other ways are competent on the basis of appropriate education, training, or experience;
- Take actions to acquire the necessary competence when necessary. This will be followed by an evaluation for the effectiveness of the actions taken. Applicable actions can include the provision of training to, the mentoring of, or the reassignment of currently employed persons, or the hiring or contracting of competent persons.
- Retain evidence of competence as documented information.

Awareness

The organization shall ensure that persons doing work under the organization's control are aware of

- The quality policy;
- Relevant quality objectives;
- Their contribution to the effectiveness of the QMS, including the benefits of improved performance;
- The implications of not conforming with the QMS requirements.

Communication

Top management of the organization will determine the required internal and external communications relevant to the QMS, including; subject of communication, time of communication, recipients of the communication, method of communication, and the issuer or initiator of the communication. Communication of the quality policy will be the responsibility of top management as mentioned in clause 2.2.2 in this Quality Manual. Interested parties internally and externally will be considered when determining the required communications. Communications initiated by customers will usually be directed to employees through emails or written official letters/notices. Similarly, stakeholders initiate communications to employees through also emails or written letter.

Documented Information**General**

This QMS includes documented information that is required by the International Standard ISO 9001 as well as documented information that is determined to be necessary by the organization for the effectiveness of the QMS.

Creating and Updating

The organization shall ensure that creating and updating documented information is done with the appropriate identification, description, format, and is reviewed and approved for suitability and adequacy.

Control of Documented Information

Information required by the QMS and by the International Standard shall be documented and controlled to ensure its availability for relevant parties, its suitability for usage wherever and whenever it is needed. Furthermore, documented information shall be sufficiently protected from loss, improper use, or loss of integrity.

For controlling documented information, the organization shall:

- Address the distribution, access, retrieval and use of documented information. This will be achieved through accordingly managing our internal network for internal interested parties as well as the information dispatched for external interested parties.
- Ensure safe storage and preserve the legibility of the documented information as well as preserve the integrity of the information in relation to updated policies, processes, etc.
- Control changes to documented information through implementing version control principles.
- Follow specified rules for retention and disposition.
- Identify and control documented information of external origin that is deemed by the organization to be necessary for planning and operation of the QMS.

The organization has determined its required documented information to be

- Quality policy;
- Quality objectives;
- Process input
- Process Control
- Process output
- Process change.

OPERATION

Operational Planning and Control

The organization will plan, implement and control the needed processes and their interactions for establishing, implementing, maintaining and continually improve the QMS. Planning will include determining inputs, outputs, sequencing, criteria and methods, resources, responsibilities, and authorities, according to Clause 4.4 of the International Standard. Furthermore, when planning for the QMS, The organization shall consider the risks and opportunities that need to be addressed according to clause 6.1 of the International Standard.

This will be accomplished through:

- Determining the requirements for the services.
- Establishing criteria for the processes and the criteria for acceptance.
- Determine the resources needed according to clause 7.1 of this Quality Manual.
- Implement control of the processes based on the criteria.
- Creating and managing all necessary documentation to ensure that the processes have been carried out as planned, and to demonstrate the conformity of services to their requirements.

Requirements for Services

Customer Communication

Customer communication will follow the guidelines previously established under clause 7.4 in the International Standard. Following the guidelines will ensure that the organization:

- Provides the necessary information regarding the services it offers; during the bidding process.
- Helps its customers adapt to major changes introduced by internal or external factors.
- Handles enquiries, contracts or special requests;
- Obtains customer feedback regarding its services. A solution process shall follow according to clause 10.2 Nonconformity and corrective action of this Quality Manual.
- Handles customer information appropriately.

Determine the Requirements for Services

The organization shall determine the requirements for services, including any applicable statutory and regulatory requirements, as well as those considered necessary by the organization. The organization shall ensure that it is able to meet the claims for services it offers as defined in the Contract Document.

Review of the Requirements for Services

The organization will conduct a review regarding its ability to meet the requirements for services before committing to supply services to customers. This review will include:

- Requirements specified by the customer and outlined in the Contract Document;
- Requirements that are necessary for legally carrying out services but is not required by the customer;
- The requirements specified by the organization as discussed in clause 8.0 of this Quality Manual;
- Statutory and regulatory requirements applicable to the services, especially new government regulations regarding universal health care.

The results of the review shall be documented according to clause 7.5 Documented Information in this Quality Manual. If there are new requirements for services, this documentation shall be updated accordingly. Changes made to the requirements of services will also be communicated to the relevant team members according to clause 7.4 Communication of this Quality Manual.

Design and Development of Services

General

The organization will establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

Design and Development Planning

For determining the stages and controls for design and development, the organization will consider:

- The nature, duration and complexity of the design and development activities;
- The required process stages, including applicable design and development reviews;
- Verification and validation activities for the required design and development;
- The responsibilities and authorities involved in the design and development process.
- The internal and external resources required for the design and development of services;
- The adequacy of the interfaces between individuals and teams involved in the design and development process;
- The requirements for subsequent provision of products and services;
- The level of control expected to be given to the relevant interested parties for the design and development process;
- Meeting the requirements for documentation according to clause xx Documented Information of this Quality Manual.

Design and Development Inputs

The organization shall determine the requirements necessary for the specific types of services to be designed and developed. The organization will consider:

- The functionality and performance required from the service being designed.
- Previous design and development activities.
- Statutory and regulatory requirements.
- Standards of practice that the organization has committed to.
- Consequences of failure considering the nature of services. For example, delays are one of the major consequences to failures in the primary services provided by our organization.

Design and Development Controls

The organization shall ensure that controls are applied to the process of design and development. This will ensure that:

- The results expected to be achieved are defined;
- Reviewing is possible for evaluating the ability of the process of design and development to meet requirements;

- Verification took place for the output of the process of design and development;
- Necessary action is taken on problems determined during the reviews, validations and verifications of the process.
- Documented information is retained for the design and development process.

Design and Development Outputs

The organization will ensure the adequacy of the outputs of the design and development process through:

- Verifying its compliance with the input requirements;
- Ensuring that they are adequate for the subsequent processes for the provision of services;
- Including the monitoring and measuring requirements as well as the acceptance criteria;
- Specifying the standard characteristics of the services that are essential for their intended purpose.
- Retaining documented information.

Design and Development Changes

The organization will manage changes made during, or subsequent to, the design and development of services to ensure that there is no adverse impact on the conformity to requirements. The changes, review results, authorization of the changes, and actions taken as countermeasures to prevent adverse impacts will be retained as documented information.

Control of Externally Provided Processes and Services

The organization does not receive products or services from external sources that are relevant to the QMS.

Production and Service Provision

Control of Production and Service Provision

The organization shall ensure the control of production and service provision through:

- Ensuring the availability of documented information that defines that characteristics of the process output, the services to be provided, or the activities to be performed as well as the results to be achieved.
- Measuring and monitoring the production and service provision using adequate resources.
- Implementing control activities as appropriate stages to apply acceptance criteria;
- Utilizing adequate infrastructure and environment for providing services;
- Assigning responsibilities and authorities based on competency;
- Validation and periodic revalidation of the process's ability to achieve the planned results, whenever the resulting output cannot be verified by subsequent monitoring or measurement;
- Implementation of error-averting actions;
- The implementation of release, delivery and post-delivery activities.

Identification and Traceability

The organization shall verify the conformity of its services whenever applicable with respect to monitoring and measurement requirements. Unique identification of the outputs will be controlled and retained as documented information with the purpose of enabling traceability.

Property Belonging to Customers or External Providers

The organization will exercise care when handling property that belongs to customers or external providers, and its loss shall be reported and retained as documented information.

Preservation

Preservation shall be applied to the outputs during production and service provision, to verify and demonstrate conformity of services.

Post-delivery activities

The organization is responsible for meeting post-delivery requirements associated with products and services. The organization shall ensure that it is meeting its post-delivery commitments by considering

- Statutory and regulatory requirements
- The potential unintended consequences associated with its products and services
- The life span of its products and services
- Customer requirements
- Customer feedback.

Control of Changes

Changes in production and service provision will be managed, for ensuring and maintaining conformity with requirements. The results of change reviews, authorizing personnel, and actions taken will be retained as documented information.

Release of Products and Services

The organization shall release its products and services only when planned arrangements associated with these products and services, have been satisfactorily completed at the appropriate stages.

Control of Nonconforming Outputs

The organization will ensure the conformity of its products and services to the applicable requirements. Products and services that do not conform the requirements will be identified and controlled to prevent their unintended use or delivery. The organization will take the necessary actions while considering the nature of the nonconformity and the stage it was detected at. Possible actions that are available for the organization to take regarding nonconformity:

- Correction
- Segregation, containment, re-work or dismissal.

- Informing the customer
- Obtaining necessary authorization for acceptance under concession

Documented Information Will Be Retained In The Event Of Nonconformity.

The retained documented information will be

- Description of the non-conformity;
- Description of the action taken to deal with the non-conformity;
- Concessions obtained when applicable;
- Authorizing personnel.

PERFORMANCE EVALUATION

Monitoring, Measurement, Analysis and Evaluation

General

In order to evaluate performance, the organization will collect and retain data that can be turned into critical information on the performance on processes, products and services. The organization will determine what will be monitored and measured, when those activities shall be performed, and when the results of the monitoring and measurement shall be analysed and evaluated. Through the analysis of such data, the organization is committed to reviewing and evaluating the performance and effectiveness of its QMS.

Customer Satisfaction

The organization is primarily concerned with customer satisfaction. To this end, the organization will monitor customers' perception of the organization, their needs and expectations.

Analysis and Evaluation

Data gathered through monitoring and measurements carried out by the QMS will be used to evaluate the conformity levels of products and services, the degree of customer satisfaction, performance and effectiveness of the QMS, effectiveness of the planning phase, the effectiveness of risk and opportunity management, performance of external providers, and the need for improving the QMS.

Internal Audit

Internal audits shall be conducted annually to provide information on the conformity of the QMS to the organization's own requirements and to the requirements of the International Standard ISO 9001: 2015. The audit will also provide information on the effectiveness of the implementation and maintenance of the system.

An audit program will be established by our internal auditors who will establish frequency, methods, and reporting. The importance of a process will influence the reporting needs and frequency. The organization's internal auditors are tasked with defining an audit criteria and scope for each audit. Our auditors have in-depth understanding of our organization, which enables them to communicate effectively with management regarding the criteria and scope of the internal auditing process. Our internal auditors know how to communicate effectively about a certain situation that needs

upper management's attention, and they usually are enabled and given the tools necessary to take appropriate correction and corrective action with no delay. The organization's internal audit information and results will be retained by our internal auditors as documented information.

Management Review

General

Top management will be responsible for reviewing the QMS on a quarterly schedule, to verify and ensure that it continues to be suitable, adequate, effective, and aligned with the strategic direction of the organization.

Management Review Inputs

Management will consider multiple streams of information when reviewing the QMS. Previous actions planned in the previous management reviews are investigated to determine their status. Management also looks at the changes that occurred to the internal or external issues that face the organization. Management will look into developing trends in customer satisfaction, process performance, corrective action, monitoring and measurement results, internal audit results, the performance of external providers, adequacy of resources, effectiveness of risk management, and discuss opportunities for improvement.

Management Review Outputs

Management reviews will result in decisions and actions related to

- Opportunities for improvement;
- Any need for changes to the QMS;
- Resource needs.

Management reviews outputs will be retained as documented information as evidence for management reviews and their results.

IMPROVEMENT

General

The organization will strive to implement any necessary actions that enable it to meet customer requirements and increase customer satisfaction. This will include

- Improving products and services
- Correcting, preventing or reducing undesired effects
- Improving the performance and effectiveness of the QMS.

Nonconformity and Corrective Action

The organization shall react to nonconformity when it occurs by:

- acting to control and correct it;
- deal with the consequences.

The organization shall evaluate the need for action to eliminate the root cause(s) of the nonconformity by:

- Reviewing and analysing the nonconformity;
- Determining the causes of the nonconformity;
- Determining if similar nonconformities exist or have the potential for occurring.

The organization shall implement any actions necessary to deal with the nonconformity. The actions taken will be reviewed for their effectiveness. Risk and opportunities associated with the nonconformity will be updated. The QMS will be updated if needed.

The organization will retain documented information regarding the nature of the nonconformities and any subsequent actions taken, and the results of any corrective action.

Continual Improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the QMS. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

CONCLUSIONS

The template quality manual presented in this paper provides a blueprint for implementing a QM based on ISO 9001: 2015 to demonstrate compliance, provide reference to internal and external stake holders regarding the organization's quality management system.

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